

Genetic Privacy Legislation and Genetic Research in Oregon

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Resources

- Genetic Privacy and Academic Medicine: The Oregon Experience
 - Cummings L & Magnusson R, *Academic Medicine*, Vol 76, No, 11 (November 2001)
- Two interviews
 - Brad Popovich, Ph.D., formerly with OHSU
 - Emily Harris, Ph.D., Kaiser Permanente

Oregon Experience

- Multnomah County Medical Society of Portland, Oregon Study Group
 - Established 1994, included geneticists and attorneys
- Genetic Privacy Act (OR SB 276)
 - Passed 1995, revised 1997&1999
- Genetic Research Advisory Committee
 - Established 1999, included a variety of representatives
- OR SB 114
 - Passed 2001

Genetic Privacy Act

■ Features

- States that “The DNA molecule contains information about an individual's probable medical future”
- Defines *genetic characteristic* as “any gene or chromosome, or alteration thereof, that is scientifically or medically believed to cause a disease, disorder or syndrome, or to be associated with statistically increased risk of development of a disease, disorder or syndrome”.

Genetic Privacy Act

■ Features

- The definition of genetic test is “a test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose a genetic characteristic”
- The definition of genetic information is “the information about an individual or family obtained from: (a) A genetic test; or (b) An individual's DNA sample”

Genetic Privacy Act

■ Features

- Establishes that an individual's genetic information is the property of the individual
- Requires informed consent in compliance with ORS 677.097 for the collection of genetic information or a DNA sample except for use in law enforcement, identification of deceased individuals, paternity testing, and anonymous research
- Mandates the destruction of a DNA sample obtained for research purposes once the original purpose is fulfilled or if requested by the person at any time

Genetic Privacy Act

■ Features

- Broadly prohibits disclosure of genetic information
- Limits the use of genetic information in employment, but does not prohibit employers from collecting genetic information
- Prohibits health insurers from using genetic information to deny coverage or set rates but does not prohibit insurers from asking for a DNA sample and conducting tests with the client's authorization

Genetic Privacy Act

■ Effects

- “The Act has the potential to affect the IRB approval of research projects, the participation of research subjects, and the funding for research”

Cummings and Magnusson 2001

Genetic Privacy Act

■ Effects

- Three areas of OHSU operations affected by the GPA
 - Informed consent
 - Ownership of genetic information
 - Security of medical information
- Two aspects of OHSU's mission affected by the GPA
 - Patient care
 - **Research**

Cummings and Magnusson 2001

Genetic Privacy Act

- Effects

- Research

- Affects informed consent process
 - Affects ownership of genetic material and information

Genetic Privacy Act

Before GPA

- Consent requirements were evaluated and determined by IRB
- Material in tissue banks property of University
- Archived tissue could be used with clinical data in medical charts upon IRB approval

After GPA

- Consent requirements established by law
- Material considered property of individual
- Anonymizing and consent requirements preclude the association of clinical data with tissue samples

Genetic Research Advisory Committee

- Included representatives from OHSU, researchers, health care provider organizations, policymakers, pharmaceutical industry, consumers, and state government
- “Mandated to study the issues surrounding genetic privacy and research and to make recommendations for changes to the GPA that would meet the needs of legitimate medical research and protect individual’s genetic privacy”

OR SB 114

■ SB114:

- States that one of the purposes of the legislation is to “define the circumstances under which a DNA sample or genetic information may be used for research”
- Establishes the Advisory Committee on Genetic Privacy and Research
 - ACGPR mandated to monitor and study evolving issues of genetic privacy and genetic research and to create opportunities for public education

OR SB 114

■ SB 114

- Mandates the Oregon Health Division to oversee IRBs that review genetic research and make rules to establish minimum standards that conform to federal policy standards
 - All IRBs subject to a minimum standard equivalent to the Federal Policy for the Protection of Human Subjects 45 CFR 46
- Defines and sets parameters for anonymous research, allows people to “opt-out”
- Mandates destruction of research samples after initial purpose is fulfilled, with some exceptions

OR SB 114

■ OR SB 114

- Prohibits recontact of individuals whose samples were used in research except under rules established by the Health Division
- Requires specific consent for genetic research, blanket research is no longer sufficient
- Mandates encryption or coding to protect individuals in non-anonymous genetic studies

OR SB 114

■ SB114:

- Changes property right to a genetic privacy right
- Refines the definition of *genetic characteristic* to include only those genetic characteristics identified via a genetic test and not those identified by family history or other means
- Includes provisions for legal recourse and penalties for violations

Interviews

- Brad Popovich, Ph.D.
 - Formerly a clinical and research geneticist at OHSU
 - Involved in crafting the 1995 Genetic Privacy Act
 - Purpose of the law was to regulate clinical genetic testing and protect patients' from privacy violations and insurance discrimination

Interviews

- Brad Popovich, Ph.D.
 - Suggests that problems identified by researchers were not directly related to the GPA but were the result of
 - 1) a lack of awareness of existing state and federal laws such as CLIA that actually had a bigger affect on research and
 - 2) lack of awareness among IRBs regarding reuse and misuse of clinical and research samples
 - Not aware of any research that was prohibited because of the GPA, however many projects were delayed after its implementation

Interviews

- Emily Harris, Ph.D.

- Epidemiologist at Kaiser Permanente in Oregon
- Identified some issues with OR SB 114
- 1) Affects studies using archived tissue
 - Blanket consent vs. specific consent
 - Clinical consent
- Definitions are not straightforward
 - E.g. “genetic information” – does it include somatic cell mutations in tumors?
- Jurisdictional issues are not well defined
 - How does the law affect participation in collaborative studies?

Conclusion

- The initial effort to draft genetic privacy legislation in Oregon was based on the recommendations of the Multnomah County Medical Society of Portland, OR
- The resulting Genetic Privacy Act was poorly received by researchers and industry and resulted in confusion and backlash
- The Genetic Research Advisory Group convened and issued recommendations to revise the law

Conclusion

- OR SB 114 amends the Genetic Privacy Act with an emphasis on genetic research, it also removes the property right given to individuals with respect to their DNA